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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,048	09/16/2003	Ming-Derg Lai	LAIM3006/REF	2552

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EXAMINER	
GUZO, DAVID	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,048	LAI ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Substitute Specification

The Substitute Specification filed 11/28/05 is acceptable and has been entered.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 8, 10, 12, 13 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Pasquini et al.

This rejection is maintained for reasons of record in the previous Office Action (mailed 8/26/05) and for reasons outlined below.

Applicant traverses the instant rejection by asserting that the claimed invention is not anticipated by Pasquini et al. because the purpose of the vaccine disclosed by Pasquini et al. is to cure B cell malignancies while the purpose of the instant invention is to treat lung, breast, ovarian or bladder cancer. Applicant asserts that due to the different treatment targets, the DNA vaccine strategies of each vaccine are distinctive. Applicant asserts that while Pasquini et al. only discloses a DNA vaccine that expresses anti-CDR_2-CDR_3 IgH and mM-CSF, the instant invention is a DNA vaccine combining N'-neu and IL-2.

Applicants' arguments filed 11/28/05 have been considered but are not persuasive. Applicants' arguments appear to be predicated upon intended use limitations read into the instant product claims. Intended use limitations carry little or no patentable weight in product claims. Pasquini et al. teaches each of the components of the recited DNA vaccine claims and hence teaches the claimed invention. The assertion that the inventors of the instant DNA vaccine intend to use it for a purpose different from that disclosed by Pasquini et al. is irrelevant when the prior art teaches the same DNA vaccine. Additionally, applicants' arguments that the instant vaccine expresses N'-neu and IL-2 and hence is different from that of Pasquini et al. are not persuasive because none of the claims rejected over Pasquini et al. recite these limitations. The rejection is therefore maintained.

Claims 1-3, 5, 8, 10-12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Glorioso et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants assert that although Glorioso et al. recites HSV multigene vectors wherein IL-2 was used for manipulating the vector, Glorioso et al. does not disclose use of the vector to treat any cancer or demonstrate the effectiveness of any HSV vector carrying the IL-2 gene. Applicants assert that Glorioso et al. fails to disclose that the HSV vectors can be used as DNA vaccines and fails to disclose DNA vaccines comprising the IL-2 and N'-neu genes as well as administering the vaccine

intramuscularly into the tumor site and the effect of suppressing tumor growth in experimental mice.

Applicants' arguments have been considered but are not persuasive. Again, applicants appear to be reading use limitations into the instant product claims. Glorioso et al. teaches each of the claimed limitations of the recited DNA vaccine claims and hence teaches the claimed invention. Even if one were to grant intended uses patentable weight in product claims, it is noted that Glorioso et al. does recite use of the HSV vectors for treatment of cancer (See columns 14-15). With regard to Glorioso et al. not teaching DNA vaccines comprising IL-2 **and** N'-neu, it is noted that none of the claims rejected over Glorioso et al. recite DNA vaccines comprising IL-2 **and** N'-neu genes. With regard to administering the vaccine intramuscularly to the tumor site, this process step is not recited in the claims under rejection over Glorioso et al. The rejection is therefore maintained.

Claims 1-5, 8, 12, 14-15, 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Cotten et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons of outlined below.

Applicants argue that Cotten et al. is directed to generation of an alternative adenovirus vector (CELO) for use as a gene delivery vector and does not recite application of the recombinant CELO virus to treat lung, breast, ovarian or bladder cancer with IL-2 and N'-neu as disclosed in the instant application. Applicants admit

that Cotten et al. discloses use of the CELO virus for gene therapy and as a tumor vaccine, but applicants argue that this is not adequate support for the contention that Cotten et al. anticipates the claimed invention.

Applicants' arguments have been considered but are not persuasive. Applicants are again reading intended use limitations into the recited produce claims. Cotten et al. teaches each of the components of the claimed DNA vaccines and hence anticipates the claimed product. Limitations concerning how the skilled artisan may subsequently use the claimed composition (to attempt to treat various cancers) are irrelevant to the nature of the composition itself. With regard to Cotten et al. not teaching DNA vaccines comprising IL-2 and N'-neu, it is noted that none of the rejected claims recite this limitation. With regard to applicants' assertion that Cotten et al.'s indication that the CELO viruses can be used as a tumor vaccine is not sufficient to support the contention that Cotten et al. anticipates the instant claims, it is noted that applicants present no data or arguments to support this assertion. In the absence of any evidence from applicants that Cotten et al. does not provide an enabling disclosure, it must be assumed that applicants' arguments are unsupported allegations. The rejection is therefore maintained.

35 USC 103(a) Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glorioso et al. or Cotten et al., either in view of Hand-Zimmermann et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants assert that the examiner has failed to make a *prima facie* case of obviousness according to MPEP 2143. Applicants assert that the references used in obviousness rejections must be from analogous arts and that the examiner has used references from non-analogous arts. Applicants then present the same arguments concerning the Glorioso et al. and Cotten et al. references as anticipatory references (see above) and assert that neither Glorioso et al. nor Cotten et al. are analogous art to the present invention because they do not teach DNA vaccines combining IL-2 and N'-neu to treat solid tumors and Hand-Zimmermann only disclose the HER-2/neu gene product and that it is amplified in a variety of cancers.

Applicants' arguments have been considered but are not persuasive. For reasons cited above, the Glorioso et al. and Cotten et al. references are anticipatory references for the subject matter of claims 1-5, 8, 10-12, 14-15, 17 and 18 and hence would be considered analogous references (to the Hand-Zimmermann reference) with regard to the claimed invention. Applicants' argument that none of the references in combination teach DNA vaccines comprising the IL-2 and N'-neu genes is not persuasive because none of the rejected claims recite DNA vaccines comprising the IL-2 and N'-neu genes. The rejection is therefore maintained.

35 USC 112, 1st Paragraph Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants amended claim 11 to recite "the **full length gene segment** (emphasis added) of Interleukin-2". The application, as filed, does not provide support for this terminology. This terminology can read on the genomic version of the IL-2 gene. The

application provides support for a "mature gene segment of Interleukin-2" which can read on a processed IL-2 gene (i.e. a cDNA, etc.). This is a NEW MATTER rejection.

35 USC 112, 2nd Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is vague in the recitation of the term "N'-neu gene". This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below. Initially it is noted that applicants have amended claims 9 and 16 to change "N neu" to "N'-neu" but did not denote the changes as required by 37 CFR 1.121 or change the status identifiers for claims 9 and 16 from "Original" to "Currently Amended". **Applicants are cautioned that any future amendments to the claims must comply with 37 CFR 1.121 and said amendments will be considered non-responsive if they do not comply.**

Applicants traverse this rejection by indicating that the definition of "N'-neu" can be found in a post filing reference (Lin et al., Mol. Therapy, 2004, Vol. 10, No. 2, pp. 290-301) and then discussing the therapeutic effect of N'-neu DNA vaccines in experimental animals. It appears that the N'-neu portion of the neu gene is the portion encoding the extracellular portion of the neu protein.

Applicants' arguments have been considered but are not persuasive. The instant claims (and specification) recite the "N'-neu **gene** (emphasis added)". If the N'-neu sequence is only a portion of the neu gene, then it is unclear what applicants mean by the "N'-neu gene".

Claim 2 is vague in that the metes and bounds of the term "mammalian promoter" are unclear. It is unclear if this term refers to promoters that are endogenous to mammalian cells or promoters (from any source) that are active in mammalian cells (i.e. a CMV promoter is active in numerous mammalian cells).

Miscellaneous:

In Claim 1, line 6, the term "fragment" is misspelled as "fragmend"

No Claims are allowed.

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID GUZO
PRIMARY EXAMINER

David Guzo
February 19, 2006